

## Efficacy of Condom Balloon Tamponade in Management of Primary Postpartum Hemorrhage

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### ABSTRACT

**Background:** Primary postpartum hemorrhage has a significant effect on maternal morbidity and mortality. Proper treatment and in time management of the patient have showed to decrease this morbidity and mortality a lot.

**Objective:** The objective of our study is to find out the efficacy of balloon tamponade in the management of primary postpartum hemorrhage.

**Material and Method:** This study was conducted in Saidu group of teaching hospital, swat from 1<sup>st</sup> august 2018 to 31<sup>st</sup> July 2019. All the patient with Primary postpartum hemorrhage were included in the study. All patients were first managed by medical therapy and when the medial therapy failed then balloon catheter tamponade were introduced and patients were noticed for stoppage of bleeding within few minutes.

**Result:** Mean age was 27.04±5.42 years. 72 patients failed from medical therapy which was managed by condom tamponade. The response rate of condom tamponade in these 72 patient was 69 (95.83%) while 3 (4.17%) did not respond. There was no significant effect of age, gravida on the response rate of Balloon tamponade.

**Conclusion:** The response rate to Balloon Catheter tamponade is high in patient with Primary postpartum hemorrhage due to uterine atony. It should be tried before preceding to other Surgical management like Be-lynch, uterine artery ligation or hysterectomy in cases of medical therapy failure.

**Key Words:** primary postpartum hemorrhage, Medical Management, Condom catheter, Response rate.

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### INTRODUCTION

Bleeding after delivery has a significant effect on mortality. postpartum hemorrhage is one of the major contributor to the world mortality of women<sup>1,2</sup>. It has been shown that 30% or more deaths occurred due to postpartum heammorrhage<sup>3</sup>. The mortality is even more when patient is not managed properly during the period of bleeding after delivery or prevention of such bleeding or with poor resources countries<sup>4,5</sup>.

The proper treatment and in time management of the patient have showed to decrease this mortality a lot<sup>4,5</sup>. The treatment have been including avoidance of held items and genital tract injury. On account of an atonic uterus, which is the most widely recognized reason for PPH, there are different methods especially pharmacological strategies are used like oxytocin, misoprostol, ergometrine and prostaglandin F2α (PGF2α)<sup>6-9</sup>. However, the aim of the treatment is to prevent the further loss of the blood by any mean which is possible only by compressing the uterine atony. For this pharmacological treatment has been shown as first line treatment in guidelines.

The uterine balloon tamponade has been shown to be second line of treatment when the

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pharmacological treatment fails<sup>10</sup>. Uterine tamponade treatment for PPH were accounted for as ahead of schedule as 1856<sup>11</sup>. They generally utilized cotton bandage to pack the uterus. Its uses decline because of the availability better drugs for contracting the uterus and knowledge about the causes of the peripartum hemorrhage, also knowing the fact the 'unphysiological' nature of tamponades due to extending the uterus the use of tamponade decrease<sup>12,13</sup>.

However, in recent years, due the inflatable technology utilization the reuse of balloon tamponade has been emerged<sup>14-16</sup>. The intrauterine balloon tamponade is cost effective and easily available and accessible<sup>17</sup>. Successful control of massive bleeding in PPH after Bakri balloon placement has been shown to 82.5%<sup>16</sup>. Anderson et al showed that there is a decrease in frequency of hysterectomy for the introduction of Barki balloon (p=?0.01)<sup>18</sup>. In postpartum hemorrhage from 7.8/10 000 deliveries before to 2.3/10 000 deliveries after the another study by Sayeba et al. found in 23 patients which are all respond completely to the condom-catheter within 15 minutes<sup>19</sup>.

Further registry on the efficacy of these tamponade is necessary. This study is aimed to notice the successfulness of the condom balloon tamponade in those patient in whom medical treatment failed. This study provides further evidence on the subject in this era on Pakistani population.

## MATERIAL AND METHODS

This study was conducted in the Saidu Group of teaching hospital, Swat from 1<sup>st</sup> August 2018 to 31<sup>st</sup> July 2019. Ethical approval was taken from the hospital ethical committee. All patients with primary postpartum hemorrhage, age range of 18 years to 50 years, term pregnancy were included in the study. All those with previous history of C-section, uterine anomaly, preterm labor, abnormal placentation and those with placental abruptions were excluded from the study. Post-partum hemorrhage was defined as the loss of more than 500ml of blood in first 24 hours of delivery. Term pregnancy was considering when the gestational period was more than 37 weeks and less than 41 weeks. Placenta abruption was the case when there was blood present between the placenta and uterus as denoted by the retro placental echogenic areas on ultrasound. Abnormal placentation was considering in those patient who placenta was attached over the internal os of the cervix (or within 2cm from it) the placenta attachment to the uterus goes beyond the endometrium.

### Management

In our study 505 patients with Post-Partum hemorrhage due to uterine atony were first managed by pharmacological therapy as per hospital protocol. Initially Oxytocin (10 units IV and then 80 units in 1000ml ringer lactate at rate of 100 ml per hour), misoprostol (1000mcg per rectal or 600 mcg sublingual) with continuous uterine massage, and bladder emptying. Medical therapy was successful in 433 patients, remaining 72 patients continued to bleed and were managed by insertion of the condom-catheter.

The condom was opened and attached to the inserting end of a Foleys catheter. Then it was introduced into the uterus of the patients. After this the condom was filled with normal saline passing through the drip set, catheter into the condom. About 250 to 400ml of fluid water or normal saline was filled or until bleeding stop. The patients were observed for any bleeding per vaginally or any deterioration in vital. Tamponade was removed after 12 to 24 hours. Failed in the cessation of bleeding were managed by the next step of Primary postpartum hemorrhage management like, b-lynch uterine artery ligation and hysterectomy.

### Data collection

Patients' name, age, parity, gravida, previous history of Primary postpartum hemorrhage was

noted. Patient amount of blood loss was noted in ml. Response of the patient in the form of bleeding cessation to medical treatment or condom Balloon Tamponade was noted as Yes or No. Respond to any treatment was define as the cessation of bleeding to the extent that it become negligible. Mean and standard deviation was calculated for quantitative variable like age. Frequency and percentage was calculated for qualitative variables which are different age groups, primipara, multipara, grand multipara, great grand multipara and uterine atony. The response to balloon tamponade was stratified among age groups, parity and past history of Primary postpartum hemorrhage. Post stratification chi square was applied and p value of <0.05 was taken significant.

## RESULTS

The mean age was 27.04±5.42 years, 239 (31.08%) patients were in age group 15-25 years, 386 (50.19%) were in age group 26-35 years and 144 (18.72%) were in age group 36-40 years. Out of total 769 patients with Primary postpartum hemorrhage, 47 (6.11%) patients were having past history of Primary postpartum hemorrhage, 64 (8.32%) were primipara, 132 (17.16%) were multiparous, 432 (56.17%) were grand multipara and 141 (18.33%) were great grand multipara. 505 (65.67%) were having uterine atony, 153 (19.895%) were having Retained Product of conception, 96 (12.48%) were having trauma to genital tract and 15 (1.95%) were of coagulopathy (Table 1).

In Total 505 cases of Primary postpartum hemorrhage due to uterine atony 433 patients respond to medical treatments, 72 case failed from medical treatment were managed by Condom tamponade in which 3 cases failed.

We analyzed the 72 cases which failed from medical therapy, 69 (95.83%) patients respond to Condom balloon tamponade while 3 (4.17%) did not respond (Table 2).

In these 72 cases, most of the patient were great grand multipara 39 (54.4%), 42 (58.33%) were in age group 26-35 years. 30 (41.67%) were due to atonic uterus and 56 (77.78%) were having no history of Primary postpartum hemorrhage.

**Table 1 Baseline Data**

		Count	Percentage
<b>Gravida/Parity</b>	Multiparous	132	17.16%
	Primipara	64	8.32%
	Grand Multipara	432	56.17%
	Great Grand Multipara	141	18.33%
<b>Age Groups</b>	15-25	239	31.08%
	26-35	386	50.19%
	36-40	144	18.72%
<b>Causes Of PPPH</b>	Uterine Atony	505	65.67%
	RPOCS	153	19.895%
	Genital Track Trauma	96	12.48%
	Coagulopathy	15	1.95%
<b>History of PPH</b>	Yes	47	6.11%
	No	722	93.89%

**Table 2 Response to Balloon tamponade**

Respond to Balloon Tamponade		
Yes	69	95.83%
No	3	4.17
<b>Total</b>	<b>72</b>	<b>100%</b>

**Table 3 Response to Balloon tamponade in each category**

		count	percentage	Response to Balloon Tamponade		
				Yes	No	P Value
<b>Parity</b>	Multipara	9	(12.5%)	8	1	0.152
	Primipara	3	(4.17%)	3	0	
	Grand Multipara	21	(29.17%)	19	2	
	Great Grand Multipara	39	(54.17%)	39	0	
<b>Age Groups</b>	15-25	13	(18.05%)	13	0	0.427
	26-35	42	(58.33%)	41	1	
	36-40	17	(23.61%)	15	2	
<b>History of PPH</b>	Yes	16	(22.22%)	16	0	
	No	56	(77.78%)	53	3	

All the grand great multipara response to balloon tamponade, only 2 patients in grand multipara and 1 patient in multipara did not respond to balloon tamponade, By Chi square test the p value for was greater than 0.005. 2 in age group 36 to 40 and one in age group 26 to 35 did not respond to

balloon tamponade while the remaining responded (table 2). All the 3 patient with failed balloon treatment were having no history of Primary postpartum hemorrhage and all the uterine atony patients respond well to balloon tamponade (see table 3).

## DISCUSSION

In our study the mean age was  $27.04 \pm 5.42$  years which was similar to the mean age of  $26.82 \pm 6.36$  found by in same type of study<sup>20</sup>. In our study we found the uterine atony in 65.67% of patient with Primary postpartum hemorrhage however it was found in 12-20% of Primary postpartum hemorrhage patient by Varner et al. which much lower than our values<sup>21</sup>.

We analyzed the 72 cases which failed from medical therapy, our response rate to balloon tamponade was 95.83%, the study done by Study by Sayeba et al. found in 23 patients which all respond completely to the condom-catheter<sup>19</sup>. Study by Asmitha et al found the success rate of condom catheter to be 94% with control of bleeding in about 6 minutes<sup>22</sup> who's result is almost similar to ours one. Lydia et al reported 4 cases with Postpartum hemorrhage achieved stoppage of bleeding successfully by condom catheter. The Rajini et al showed balloon tamponade was effective in 126(90.4%) cases<sup>15</sup>. Yashyita showed these methods a more effective when it is used with continuous Oxytocin infusion<sup>23</sup>. The higher response rate may be real in our result as it coincided with many other studies abroad<sup>15,22-27</sup>.

However, another study showed a bit lower rate of success and high rate of 3<sup>rd</sup> line treatment for PPH like hysterectomy. 13 out of 22 patients (59.1%) recovered fully after balloon catheter for PPH. With 7 patients (31.8%) required hysterectomy<sup>28</sup>.

In our study the age groups, different causes of PPH did not showed significant relationship between the effectiveness of balloon catheter and these. Out of 4 hyper coagulopathy patients 3 respond to condom catheter while 1 didn't, the study by Rashmi et al. showed the 2 women with hypercoagulability and PPH have successfully respond to condom-catheter<sup>29</sup>. Emmanuelle et al also showed that there is demographic and obstetric data of the patients did not affect the success or failure<sup>30</sup>.

The balloon catheter is effective, less cost<sup>31</sup> and less training require for insertion of balloon. Also there are lower failure rate, further more in others study the time require for insertion is also about 1 minute<sup>23</sup>. So this effective method for controlling the bleeding from PPH. It should be used promptly after the failure of medical treatment of PPH for decreasing its complications.

## CONCLUSION

The response rate to Balloon Cathetertamponade is high in patient with cases of Primary postpartum hemorrhage due to uterine atony. It should be tried before preceding to other management like b-lynch uterine artery ligation or hysterectomy in cases of medical therapy failure.

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**DATA SHARING STATEMENT:** The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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#### **AUTHOR'S CONTRIBUTION**

Following authors have made substantial contributions to the manuscript as under

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|-----------------|-------------------------------------------------------------------------------------------------------------------------------|
| <b>Begam Z:</b> | Concept and design of study, Collection of data, statistical analysis<br>Writing of manuscript, critical review of manuscript |
| <b>Zahir N:</b> | Analysis and interpretation of data, statistical analysis                                                                     |
| <b>Sadaf F:</b> | Data collection, bibliography                                                                                                 |

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.